K123528

510(k) Summary

as required by 21 CFR Part 807.87(h)

DEC 2 0 2012

Submitter:	Elaine Chang Regulatory Technical Specialist Siemens Medical Solutions USA, Inc. 810 Innovation Dr Knoxville, TN 37932 USA
Telephone Number:	(865) 218-2873
Fax Number:	(865) 218-3019
Name / Address of Manufacturer:	Siemens Medical Solutions USA, Inc Molecular Imaging 2501 N. Barrington Road Hoffman Estates, IL 60192 USA

Date of Submission:	November 15, 2012

Identification of the product

Device Proprietary Name:	Scenium 3.0
Common Name:	Picture Archiving and Communication System
Classification Name:	Picture Archiving and Communication System per 21 CFR 892.2050 Emission Computed Tomography System per 21 CFR 892.1200
Product Code:	LLZ and KPS
Classification Panel:	Radiology
Device Class:	Class II

Marketed Devices to which Equivalence is claimed

Device	Manufacturer	510(k) Number
Scenium 2.0	Siemens Medical Solutions USA, Inc	K121074
NeuroTrans3D	Segami Corporation	K043441
Brass	Hermes Medical Solutions	K021656

Device Description:

Scenium 3.0 display and analysis software enables visualization and appropriate rendering of multimodality data, providing a number of features which enable the user to process the acquired image data. Scenium 3.0 is post processing and does not control the scanning features of the system.

Indications for Use:

The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET and SPECT scans.

The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations.

The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with existing scans derived from FDG-PET, amyloid-PET, and SPECT studies and calculation of uptake ratios between regions of interest.

Technological characteristics:

The software is similar in uses and applications to the predicate devices. Both the device and predicates are used to assist the Clinician with the visual evaluation, assessment and quantification of pathologies derived from brain scans.

Safety and Effectiveness:

The device is designed and manufactured under Quality System Regulations as outlined in 21 CFR 820. All requirements of Emission Computed Tomography system standards (21 CFR 892.1200) and Picture Archiving and Communications System (21 CFR 892.2050) are met, and software is in compliance with ISO 14971 and ISO 62304.

Substantial Equivalence:

Based on the above considerations, Siemens Medical Solutions USA, Inc believes that the Scenium 3.0 software is substantially equivalent to the predicate devices. The device and the

predicate devices are all post-processing and provide similar features of visualization and numerical data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 20, 2012

Siemens Medical Solutions USA, Inc.
% Ms. Elaine Chang
Regulatroy Technical Specialist
810 Innovation Drive
KNOXVILLE TN 37932

Re: K123528
Trade/Device Name: Scenium 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ and KPS
Dated: November 15, 2012
Received: November 16, 2012

Dear Ms. Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris -S

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: Scenium 3.0

Indications for Use:

The Scenium display and analysis software has been developed to aid the Clinician in the assessment and quantification of pathologies taken from PET and SPECT scans.

The software is deployed via medical imaging workplaces and is organized as a series of workflows which are specific to use with particular drug and disease combinations.

The software aids in the assessment of human brain scans enabling automated analysis through quantification of mean pixel values located within standard regions of interest. It facilitates comparison with existing scans derived from FDG-PET, amyloid-PET, and SPECT studies and calculation of uptake ratios between regions of interest.

Prescription Use___X___ (Part 21 CFR 801 Subpart D) OR Over the Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123528